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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/26/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/834,312	Applicant(s) ILLUM ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 20-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 8-14, 20-26 and 28-33* is/are rejected.

7)☒ Claim(s) *4,6,7 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114 and pre-amendment B filed on 09/05/02.

Claim Objections

1. Claims 8-14 and 30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1 is consisting essentially of fexofenadine or pharmaceutically acceptable salt thereof and a pharmaceutical carrier. The dependent claims therefore cannot comprise of other ingredients.

DUPLICATE CLAIMS

2. Applicant is advised that should claim 8 be found allowable, claim 30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 5 and 26 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite material that is able to complex with the fexofenadine or the pharmaceutically acceptable salt thereof without a description of what the complex is in the specification.

6. Claims 5 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "wherein the pharmaceutical excipient is a material which is able to complex with the fexofenadine or pharmaceutically acceptable salt thereof" is indefinite because it is not clear what form is the complex. Is the excipient that is a material covalently or ionically bound to the fexofenadine or to the pharmaceutically acceptable salt or is the excipient material associated or integrated with the fexofenadine or to the pharmaceutically acceptable salt? The phrase "which is able to" ambiguous because it appears that there is no complex between the "material" and the fexofenadine or the pharmaceutically acceptable salt and that a complex may be formed. Is there or is there not a complex?

Claim Rejections - 35 USC § 102

7. The rejection of claims 1-4, 9-14, 20 and 22 under 35 U.S.C. 102(b) as being anticipated by Cupps et al. (US 5.691,370) is withdrawn because claim 1 is amended to recite consisting essentially of (i) fexofenadine or the salt and (ii) pharmaceutical excipient.

8. Claims 1-3, 14, 20-22, 30 and 33 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US 6,120,803).

Applicants ague that Wong does not teach a pharmaceutical excipient that increases the solubility of fexofenadine or its salts and that Wong does not disclose such excipient. Furthermore, applicants sate that the claimed carrier is not any carrier but includes the carriers that have specific property.

9. Applicant's arguments filed 09/05/02 have been fully considered but they are not persuasive.

Applicants broadly claim excipient and Wong teaches excipients. Applicants have not recited any specific excipient or recited a list of excipients from which to select from. A mere recitation that the excipient increases the solubility of fexofenadine or its salts does not carry any patentable weight. Applicants claim excipient and an excipient is an excipient without a recitation of a specific excipient. There is no claim to any specific excipient.

It may be noted that if applicants have recited---where said excipient is selected from the group consisting of ---, the argument would have been persuasive if the cited prior art does not teach any of the excipients within the group listed.

Wong discloses a composition comprising fexofenadine, surfactants, carriers and excipients (column 5, lines 13-19, 44-49 and 56-61, column 6, lines 13-25, column 17, lines 22-

38 and claims 4 and 6). Claims 3 and 4 teach hydroxypropyl cellulose, carboxymethylcellulose alginates, sodium carboxymethyl cellulose, corn starch granules and cross-linked polyvinylpyrrolidone. The teachings of Wong meet the limitations of the claims.

10. Claims 1-3, 12-14 and 20 remain rejected under 35 U.S.C. 102(2) as being anticipated by Lech (US 6,027,746).

Applicants ague that Lech does not teach pharmaceutical excipient that increases the solubility of fexofenadine or its salts in water.

11. Applicant's arguments filed 09/05/02 have been fully considered but they are not persuasive.

A mere recitation that the excipient increases the solubility of fexofenadine or its salts does not carry any patentable weight. Applicants claim excipient and an excipient is an excipient without a recitation of a specific excipient. There is no claim to any specific excipient.

Lech discloses a pharmaceutical composition comprising fexofenadine (column 4, line 7), excipients (column 4, lines 52-56) and poloxamer 407 (column 6, lines 35-61). See also abstract and claims 1-8. The teachings of Lech meet the limitations of the claims.

12. Claims 1-3, 12-14 and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Ahlgren et al. (US 6,117,452).

Applicants ague that Ahlgren does not teach a pharmaceutical excipient that increases the solubility of fexofenadine or its salts.

13. Applicant's arguments filed 09/05/02 have been fully considered but they are not persuasive.

A mere recitation that the excipient increases the solubility of fexofenadine or its salts does not carry any patentable weight. Applicants claim excipient and an excipient is an excipient without a recitation of a specific excipient. There is no claim to any specific excipient. It may be noted that the claims directed to applicants excipient is not included in the above rejection.

Ahlgren discloses a composition comprising fexofenadine, excipients and surfactants such as Poloxamers, Tweens and Spans (column 2, lines 7-65, column 6, lines 9-38, and claims 3, 4, 8, 13 and 21). Ahlgren teaches that the composition is formulated into tablets, pills, capsules, troches and liquid suspension and specifically states that transdermal, buccal and nasal dosages are contemplated (column 6, lines 28-30). The teachings of Ahlgren meet the limitations of the claims.

14. Claims 1-3, 9-11, 14, 20-22 and 33 remain rejected under 35 U.S.C. 102(a) as being anticipated by pages 1189 to 1190 of 1998 physician desk reference.

Applicants ague that the composition in the PDR reference is not adapted for administration to the eye or nose and that none of the excipients in the PDR reference acts to increase the solubility of fexofenadine in water.

15. Applicant's arguments filed 09/05/02 have been fully considered but they are not persuasive.

A mere recitation that the excipient increases the solubility of fexofenadine or its salts does not carry any patentable weight. Applicants claim excipient and an excipient is an excipient without a recitation of a specific excipient. There is no claim to any specific excipient in the claims rejected above.

The 1998 physician desk reference discloses a capsule dosage form of fexofenadine (ALLEGRA™). The dosage form comprises excipients and other additives such as iron oxide, gelatin, silicon dioxide, titanium dioxide and sodium lauryl sulfate. See pages 1189-1190, 1998 PDR. This publication on ALLEGRA meets the limitations of the claims.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 5, 8 and 30 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wong et al. (US 6,120,803).

Wong clearly teaches a composition comprising fexofenadine and an excipient and would anticipate the claims because any excipient would complex with the fexofenadine. The type of complexation is not defined by the claims or disclosed in the written description of the invention. Although, Wong does not specifically state that the excipient is able to complex with fexofenadine, but the since the composition comprises excipient and fexofenadine, it is inherent that the excipient would be able to complex with the fexofenadine or in the alternate is would be obvious that a complex would form between the excipient and fexofenadine. In the absence of a showing the excipient in the composition of Wong would complex with fexofenadine in the composition.

18. Claims 23, 24, 26, 28, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over pages 1189 to 1190 of 1998 physician desk reference.

The 1998 physician desk reference discloses a capsule dosage form of fexofenadine (ALLEGRA™). The dosage form comprises excipients and other additives such as iron oxide, gelatin, silicon dioxide, titanium dioxide and sodium lauryl sulfate. See pages 1189-1190, 1998 PDR. The amount of fexofenadine in the composition is 60 mg and the PDR does not report the amount in terms of concentration.

The PDR teaches the claimed composition except that the amount of the active ingredient is not reported in concentration units. One having ordinary skill in the art would know routine experimental procedure of determining the concentration of fexofenadine in allegra and of optimizing the composition in allegra as an effective antihistamine. Therefore, it would have been obvious to one of ordinary skill in the at the time the invention was made to prepare the allegra disclosed in the 1998 PDR because allegra comprises 60 mg of fexofenadine. But generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

19. Claims 23-26, 28, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cupps et al. (US 5,691,370).

Cupps discloses a pharmaceutical comprising terfenadine or terfenadine carboxylate, carriers lactose, sucrose, starches, propylene glycol, glycerin and mannitol and suspending agents such as tragacanth and sodium alginate (column 16, line 23 to column18 line 48 and claim 1). Cupps specifically teaches intranasal and intraocular dosage form and discloses that topical intraocular composition comprises poloxamer vehicles (column 18, lines 13-48).

Cupps teaches the claimed composition except that Cupps does not teach the concentration of fexofenadine. But generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition of Cupps through routine experimentation to achieve the amount of the fexofenadine that will provide the desired antihistamine effect.

20. Claims 4, 6, 7 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
September 24, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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